UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**Civil Action No. 3:16-md-2738-MAS-RLS** **MDL No. 2738**

THIS DOCUMENT RELATES TO

Converse v. Johnson & Johnson
No. 3:18-cv-17586-MAS-RLS

Newsome v. Johnson & Johnson
No. 3:18-cv-17146-MAS-RLS

Rausa v. Johnson & Johnson
No. 3:20-cv-02947-MAS-RLS

THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN RESPONSE AND OPPOSITION TO DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT, LLC'S MOTION TO EXCLUDE THE OPINIONS OF DR. DANIEL CLARKE-PEARSON

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The Plaintiffs' Steering Committee ("PSC") submits this Memorandum of Law in response and opposition to *Defendants Johnson & Johnson and LLT Management, LLC's Motion to Exclude the Opinions of Dr. Daniel Clarke-Pearson* (ECF Doc. 33007) ("Motion"). For the foregoing reasons, this Court should deny Defendants' Motion.

I. INTRODUCTION

The PSC has produced evidence and expert testimony from Dr. Daniel Clarke-Pearson, a gynecologic oncologist, that exposure to Johnson's *Baby Powder* and *Shower-to-Shower* (collectively "Talcum Powder Products") are capable of causing ovarian cancer in plaintiffs Pasqualina Rausa, Hilary Converse, and Tamara Newsome. In reaching his opinions he applied reliable methodology. Accordingly, the Defendants' Motion to Exclude Dr. Clarke-Pearson must be denied.

To be clear, the question at this time is not whether Dr. Clarke-Pearson is right in his conclusions, but rather whether he is qualified to offer his opinions, and whether he applied reliable methodologies in reaching his opinions so that they are admissible at trial.

With respect to qualifications, there is no question that Dr. Clarke-Pearson is a nationally and internationally recognized expert in the field of gynecologic oncology. In fact, Defendants do not dispute that Dr. Clarke-Pearson is qualified to offer an expert opinion in this matter. The only issue then is methodology. With

respect to methodology, Dr. Clarke-Pearson followed a rigorous and accepted methodology in assessing and weighing the scientific evidence on causation in the same manner he uses in his professional work outside of litigation. These methods include employing the causation framework and considerations described by Sir Bradford Hill in his seminal 1965 address[1] ("Hill Principles") and the principles of evidence-based medicine.

As set forth in the PSC's Opposition to Defendants' Motion to Exclude Plaintiffs' Experts' General Causation Opinions ("General Causation Response"), there are multiple robust lines of scientific evidence relevant to the causation question at issue here. This evidence includes both published, peer-reviewed epidemiological and non-epidemiologic studies. Notwithstanding Defendants' protestations, the overwhelming majority of these observational studies, irrespective of study design or population studied, found a *positive association* (*i.e.,* a hazard or odds ratio > 1) between increased risk of ovarian cancer and genital talcum powder use. Importantly, within the past three months, further confirmation of this association was reported by NIH researchers in one of the most comprehensive talcum powder studies to have ever been conducted, reaffirming the existence of a positive link between genital talc use and ovarian cancer.[2]

[1] Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc'y Med. 295 (1965), attached as **Exhibit 1**.

[2] O'Brien, KM, Wentzensen N, et al., Intimate Care Products and Incidence of Hormone-Related

In addition to this consistent, positive and largely undisputed epidemiologic research, the PSC's General Causation Response sets forth published biologic, mechanistic and other non-epidemiologic evidence to further support the conclusion that the observed association between talcum powder and ovarian cancer is indeed a *causal association*. In fact, within the past two months, the International Agency for Research on Cancer (IARC) classified talc as "probably carcinogenic to humans."[3] IARC confirmed the classification of talc containing asbestos is a known human carcinogen that can cause ovarian cancer.[4]

With the score mounting against Defendants, they try a new tactic: they move the goal posts. Although their own expert, Dr. Michael Finan, recently stated in his expert report "[d]ifferential diagnosis is not used in medical practice to determine

Cancers: A Quantitative Bias Analysis, J Clin Oncol 00:1-15(2024), attached as **Exhibit 2**.

[3] IARC Working Group, Carcinogenicity of Talc and Acrylonitrile, Lancet Oncol (July 5, 2024), attached as **Exhibit 3.**

[4] IARC Monographs evaluate the carcinogenicity of talc and acrylonitrile, Questions & Answer and Press Release, Talc and Acrylonitrile (July 5, 2024), at 4-5, ("There were numerous cancer studies in humans that consistently showed an increase in the incidence of ovarian cancer among women reporting use of body powder in the perineal region. However, the Working Group concluded that a causal association could not be fully established because the increase could potentially be explained by contamination of the talc with asbestos (which has been documented) or by biases arising from the studies' methodology. . . . The Working Group also noted that contamination of talc products with asbestos has been documented and that industry standards used to assess talc in cosmetic and pharmaceutical products have often not been sufficiently sensitive to rule out contamination with asbestos. . . . . "Talc containing asbestos" remains a part of the definition of asbestos (classified as *carcinogenic to humans*, Group 1, by the *IARC Monographs* programme in 2009 in Volume 100C) and was not included in the present evaluation (Volume 136). There is *sufficient* evidence that asbestos causes mesothelioma and cancers of the lung, larynx, and ovary in humans."), attached as **Exhibit 4**.

the cause of cancer,"[5] Defendants attempt to change their own rules and argue that Dr. Clarke-Pearson's opinions should be excluded because he did not properly conduct a differential diagnosis. Consistent with 3rd Circuit case law, Dr. Clarke-Pearson did in fact conduct a differential diagnosis. He thoroughly considered the plaintiff's medical history and exposure to talcum powder, then systematically ruled in and ruled out all potential causes of her ovarian cancer. He ultimately concluded that the genital use of talcum powder was a substantial contributing case of ovarian cancer in these three plaintiffs.

In seeking to strike Dr. Clarke- Pearson's opinions, Defendants devised a methodologic challenge when they actually disagree with his case specific conclusions, conduct contrary to the mandate of *Daubert* and its progeny. Of course, a "battle of the experts" does not provide an appropriate *Daubert*-related basis for excluding an expert's opinion that is based on sound scientific methodology.[6] Any

[5] Expert Report of Michael A. Finan, MD, May 28, 2024, at 65, attached as **Exhibit 5**.

[6] *See S.E.C. v. Lucent Techs., Inc.*, 610 F. Supp. 2d 342, 351 (D.N.J. 2009) (quoting *Oddi v. Ford Motor Co.*, 234 F.3d 136, 146 (3d Cir. 2000)); *Dzielak v. Whirlpool Corp.*, 2017 WL 1034197, at *26 (D.N.J. Mar. 17, 2017); *Lansford-Coaldale Joint Water Auth. v. Tonolli Corp.*, 4 F.3d 1209, 1216 (3d Cir. 1993) ("'[I]n a battle of the experts, the factfinder 'decide[s] the victor.'") (alteration in original) (quoting *Mendes-Silva v. United States*, 980 F.2d 1482, 1487 (D.C. Cir. 1993)); *In re Biogen '755 Patent Litig.*, 2018 WL 3586271, at *11 (D.N.J. July 26, 2018); *Lanzilotti by Lanzilotti v. Merrell Dow Pharm. Inc.*, 1986 WL 7832, at *3 (E.D. Pa. July 10, 1986) (the experts for both sides differed as to what interpretations should be given to various data. "The case was thus a classic battle of the experts, a battle in which the jury must decide the victor."); *In re Gabapentin Patent Litig.*, 2011 WL 12516763, at *10 (D.N.J. Apr. 8, 2011) (concluding that defendants' critiques of plaintiffs' experts' methodology and inconsistent conclusions presented "a battle of the experts, and both sides will be permitted to present expert testimony on these issues and to cross-examine the other side's expert witnesses.").

differences in expert opinions should be explored on cross-examination and not excluded as unreliable.

Defendants' Motion to Exclude Dr. Clarke-Pearson should be denied for three reasons:

1. Dr. Clarke-Pearson conducted a case-specific analysis of each plaintiff. He methodically considered the case-specific facts of each case, as well as each known risk factor and protective factor for ovarian cancer, ruling in and ruling out factors relevant to each plaintiff. This methodology is precisely the differential diagnosis Defendants argue he did not conduct.
2. Defendants' arguments regarding Dr. Clarke-Pearson's deposition testimony mischaracterize the record. Even if Defendants had not adulterated his testimony and quoted it out of context, their arguments go to the weight of the evidence, not its admissibility.
3. Dr. John Godleski's opinions are not dispositive to the admission of Dr. Clarke-Pearson's opinions.

At best, Defendants' challenges to differences in the interpretation of scientific evidence raise nothing more than jury-appropriate questions. Accordingly, Defendants' motion must fail.

II. DR. CLARKE-PEARSON'S BACKGROUND AND METHODOLOGY

Dr. Clarke-Pearson is a gynecologic oncologist certified by the American Board of Obstetrics and Gynecology. [7] A full professor at the University of North Carolina-Chapel Hill, Department of Obstetrics and Gynecology, Dr. Clarke-Pearson belongs to the Society of Gynecologic Oncology (SGO) and is a past President of the SGO as well as a member of the SGO Ethics Committee. For more than 40 years, Dr. Clarke-Pearson has been involved in the treatment, teaching, and research of gynecologic cancers, including ovarian cancer. His clinical work has included surgery, chemotherapy administration, clinical trials, and oversight of Obstetrics and Gynecology residents. He has published over 250 peer-reviewed manuscripts, written over 50 medical textbook chapters, and edited three medical textbooks.[8]

Dr. Clarke-Pearson's methodology included a systemic review of the relevant literature, including peer-reviewed papers, original research, case-controlled studies, cohort studies, meta-analysis studies, and systemic analyses. Additionally, he reviewed relevant textbooks and sought additional materials as needed. He "approached this research with the same scientific rigor" he has employed in his "own clinical, academic, and research practice."[9] Grounded in 40 years of

[7] Third Amended Expert Report of Daniel Clarke-Pearson, MD, May 28, 2024 ("Clarke-Pearson Rep."), Exhibit A (Clarke-Pearson CV), attached as **Exhibit 6**.
[8] Clarke-Pearson Rep. at 3.
[9] *Id.* at 4.

knowledge and experience as a gynecologic oncologist, he assessed the data "objectively and critically," considering study strengths and weaknesses by assessing "design, power, reputation of author(s), quality of journal, and potential biases," among other factors.[10] Incorporating a weight of the evidence approach, he assessed the data and information according to its strength, and applied a Bradford Hill analysis.[11] Dr. Clarke-Pearson concluded "to a reasonable degree of medical and scientific certainty, that the use of talcum powder products, including Johnson's Baby Powder and Shower-to-Shower, applied to the perineum of women, can cause EOC [Epithelial Ovarian Cancer]."[12]

Importantly, the methodology employed by Dr. Clarke- Pearson to opine on general causation was found to be reliable and admissible by this Court following an extensive Daubert process.[13] Dr. Clarke-Pearson then conducted a case-specific analysis for three bellwether plaintiffs in this litigation: Hilary Converse, Tamara Newsome and Pasqualina Rausa. In each case, he reviewed all the available medical records, deposition testimony, Plaintiff Profile Form and Dr. Godleski's expert report or pathological findings.[14] He then considered all the relevant factors that

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[10] *Id.*
[11] *Id.*
[12] *Id.* at 2.
[13] *See In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prod. Liab. Litig.*, 509 F.Supp.3d 116 (D.N.J. 2020).
[14] Second Amended Rule 26 Expert Report of Daniel Clarke-Pearson – Converse ("2d Amd. Converse Rep."), May 28, 2024, at 17, attached as **Exhibit 7**; Second Amended Rule 26 Expert Report of Daniel Clarke-Pearson – Newsome ("2d Amd. Newsome Rep."), May 28, 2024, at 18,

could contribute to the development of the plaintiff's ovarian cancer, forming a differential diagnosis.[15]

III. THE MEDICAL CONSENSUS: TALCUM POWDER IS A RISK FACTOR EPITHELIAL FOR OVARIAN CANCER

In formulating his case-specific opinions, Dr. Clarke-Pearson considered known risk factors and protective factors, ruling in and ruling out associated factors for each plaintiff.

A. The Clinical Definition Of "Risk Factor"

In clinical medicine, the term "risk factor" is often used to describe something that increases the chance of developing a disease.[16] An "evidence-based medicine" approach for doctors is very similar to a Bradford-Hill analysis, as "medical decisions should be based on quality evidence."[17] Cause and risk factor are often used interchangeably, assuming there exists a plausible biological mechanism to explain the association.[18] This methodology for determining cancer causality merges

attached as **Exhibit 8**; Second Amended Rule 26 Expert Report of Daniel Clarke-Pearson – Rausa ("2d Amd. Rausa Rep."), May 28, 2024, at 18, attached as **Exhibit 9**.

[15] 2d Amd. Converse Rep. at 17; 2d Amd. Newsome Rep. at 18; 2d Amd. Rausa Rep. at 18.

[16] *See* National Cancer Institute, *NCI Dictionary of Cancer Terms*, available at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/risk-factor, attached as **Exhibit 10**.

[17] Wendy R. Brewster, *Epidemiology of Commonly Used Statistical Terms and Analysis of Clinical Studies*, Clinical Gynecologic Oncology at 579-585 (9th ed. 2017), attached hereto as **Exhibit 11**.

[18] *See* Deposition of Daniel L. Clarke-Pearson, M.D., February 4, 2019 at 80:3-5 ("They're virtually the same. A risk factor describes a cause. It does not affect every woman that has that risk factor."), attached hereto as **Exhibit 12**; Third Amended Expert Report of Judith Wolf, MD("Wolf Rep."), May 28, 2024 at 3 ("A causative risk factor is one that increases the chances of developing a disease by means of a known or predictable mechanism. In other words, it is more than a mere association."), attached as **Exhibit 13.**

traditional epidemiology, molecular research, and public health decision-making.[19] In addition to epidemiological studies reporting a consistent association of talcum powder use and the risk of ovarian cancer, there are numerous peer-reviewed medical publications, particularly in recent years, describing and listing talcum powder use as a risk factor for epithelial ovarian cancer, thus incorporating mechanism. In addition to talcum powder and asbestos exposure, other risk factors that have been linked to epithelial ovarian cancer (EOC) include increasing age, nulliparity, infertility, endometriosis, obesity, polycystic ovarian syndrome, use of an intrauterine device, history of pelvic inflammatory disease, and cigarette smoking (for mucinous carcinoma). Protective factors (*i.e.,* those factors associated with a decreased risk of EOC) include previous pregnancy, history of breastfeeding, oral contraceptives, and tubal ligation.[20]

It is important to note that risk factors can interact with each other or act independently. They can act in a cumulative, additive, and/or synergistic fashion.[21] Talcum powder usage is often referred to as a "lifestyle risk factor" and therefore, a

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[19] Paolo Vineis, *et al., Causality in Cancer Research: A Journey through Models in Molecular Epidemiology and Their Philosophical Interpretation*, Emerging Themes in Epidemiology (2017) 14:7 ("[C]ausal reasoning is based on both 'evidence of difference-making' (e.g., associations) and on 'evidence of underlying biological mechanisms.' This is important not only to understand cancer etiology, but also to design public health policies that target the right *causal* factors at the macro- level."), attached as **Exhibit 14**.

[20] *See* Wolf Rep. at 4.

[21] Song Wu, *et al., Evaluating Intrinsic and Non-Intrinsic Cancer Risk Factors*, Nature Commc'n (2018) 9:3490 ("Non-intrinsic and intrinsic risk factors often do not act independently as we have highlighted, and the most likely scenario is that they cooperate to cause cancer."); attached as **Exhibit 15**.

modifiable and preventable cancer cause.

B. The Medical Literature Recognizes Talcum Powder as a Risk Factor for Epithelial Ovarian Cancer

There are multiple peer-reviewed publications that recognize the genital use of talcum powder as a risk factor for epithelial ovarian cancer. Some examples follow.

- **Hunn and Rodriguez (2012):** in a review article titled "Ovarian Cancer: Etiology, Risk Factors, and Epidemiology" include "perineal talc exposure" as an "inflammatory risk factor," describing the "[e]vidence demonstrating an association between talc use and an increased risk of ovarian cancer suggests that environmental toxins can enter the lower genital tract and migrate upward through the uterus and fallopian tubes to enter the peritoneal cavity and act as ovarian carcinogens."[22] This article is cited by the National Cancer Institute in its Physician Data Query: Ovarian, Fallopian Tube, and Primary Peritoneal Cancers Prevention (PDQ®)–Health Professional Version: Who is at Risk?[23]

- **Mallen *et al.* (2018):** in a review titled, "Risk Factors for Ovarian Carcinoma," included in its risk factor chart genital powder use as a "Lifestyle Risk Factor" for all serous, endometrioid and clear cell carcinomas.[24]

- **Park *et al.* (2018):** described the increased risk in the African-American population: "In particular, talc powder use is highly prevalent in the African-American community and has been found to be associated with increased risk of ovarian cancer in this and other studies."[25]

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[22] Hunn J and Rodriguez G, Ovarian Cancer: Etiology, Risk Factors, and Epidemiology (2012), Clinical Ob Gyn 55:1 at 6, attached as **Exhibit 16.**

[23] National Cancer Institute, Ovarian, Fallopian Tube, and Primary Peritoneal Cancers Prevention (PDQ®)–Health Professional Version: Who is at Risk?, March 6, 2024, attached as **Exhibit 17**.

[24] Mallen A, Townsend M, *et al.*, Risk Factors for Ovarian Carcinoma, Hematol Oncol Clin N Am (2018) at 4, attached as **Exhibit 18**.

[25] Park H, Schildkraut J, *et al.*, Benign Gynecological Conditions are Associated with Ovarian Cancer Risk in African-American Women: a Case-Control Study, Cancer Causes & Control (2018) at 8, attached as **Exhibit 19** (noting "The risk associated with serous ovarian cancer in women

- In a textbook chapter titled Ovarian Cancer Prevention and Screening, the authors described talc use as a "lifestyle factor," stating that the "[u]se of talc in the genital area has been consistently shown to increase the risk of OC and therefore is not recommended."[26]

- The Institute of Medicine (IOM) in the "state of the science" treatise on ovarian cancer identified talc and asbestos as inflammatory factors associated with ovarian cancer in the biological plausibility section.[27]

- **Phung, *et al.* (2022):** The Ovarian Cancer Association Consortium, a consortium composed of leading ovarian cancer researchers in the world, listed talcum powder use as a well-established risk factor for ovarian cancer.[28]

1. Ovarian Cancer Subtypes

It is customary to refer to ovarian, fallopian tube, and primary peritoneal cancer as a single entity, distinguishing histologic subtypes only when appropriate. The epidemiological literature commonly does not distinguish between subtypes, nor do treatises by medical societies or governmental agencies (*e.g.,* IARC, Health Canada, FDA). For example, the National Cancer Institute (NCI) treats Ovarian, Fallopian Tube, and Primary Peritoneal Cancer as a single cancer, as does the

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with a history of multiple conditions was higher than individual associations observed in any one gynecologic condition. This observation may suggest a possible additive or synergistic effect on tumorigenesis influenced by the pro-inflammatory milieu from an increased burden in the number of benign conditions. Increased risk of serous carcinoma in women with other pro- inflammatory risk factors has been reported, *most notably in talc users*.") (emphasis added).

[26] Eeles R, Berg C., *et al*., *Cancer Prevention and Screening: Concepts, Principles and Controversies*, Chapter 23 at 337 (2018), attached as **Exhibit 20.**

[27] IOM Comm. On the State of the Science in Ovarian Cancer Research, Ovarian Cancers: Evolving Paradigms in Research and Care (2016) at 110, attached as **Exhibit 21**.

[28] Phung, MT, *et al.*, *Effects of risk factors for ovarian cancer in women with and without endometriosis.* Fertility and Sterility. Vol. 118, No. 5. 960-969 (2022), attached as **Exhibit 22.**

American College of Obstetrics and Gynecology (ACOG). A recent review seminar published in the Lancet (2019), titled "Epithelial ovarian cancer" provides a further example. Although the distinct histological subtypes are discussed in this article, epithelial ovarian cancer is addressed as a whole, including risk factors.[29]

Defendants argue that "clear cell carcinoma – the subtype with which Ms. Converse was diagnosed – shows no association with talcum powder use."[30] That statement is simply untrue. Genital talcum powder use has been associated with at least a 24% statistically significant increased risk of invasive clear cell ovarian cancer (OR, 1.24; 95% CI, 1.01-1.52).[31]

IV. LEGAL ARGUMENT

A. Legal Standards For The Admissibility Of Expert Causation Opinions

The PSC incorporates the *Plaintiffs' Steering Committee's Brief Regarding the Rule 702 Standard* (hereinafter "*PSC's Rule 702 Brief*") and highlights the following important points of particular relevance to the outcome this motion:

First, Fed. R. Evid. 702 has "a liberal policy of admissibility."[32] Exclusion of

[29] Lheureux S, Gourley C, *et al., Epithelial Ovarian Cancer*, The Lancet 393:1240–53 (2019), attached as **Exhibit 23**.
[30] Motion at 2.
[31] Terry KL, Karageorgi S, et al., Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls, Cancer Prev. Res. 2013: 6:817, attached as **Exhibit 24**; *see also* Schildkraut, JM, *et al.* Association between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study (AACES). Cancer Epidemiol Biomarkers Prev; 25(10); 1411–7 (any genital use of powder and nonserous EOC OR 1.63 (1.04-2.55)), attached as **Exhibit 25.**
[32] *Geiss v. Target Corp.*, 2013 WL 4675377, at *4 (D.N.J. Aug. 30, 2013) (citing, *inter alia, Pineda*

expert testimony is only appropriate when such testimony qualifies as irrelevant or "junk science"[33] Otherwise, the trial court should cede complex issues to the jury and rely on the traditional safeguards of the adversary system—active cross-examination, presentation of contrary and competing expert testimony—rather than exclude from juror scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.[34]

Second, differing and competing expert opinions, precisely what Defendants have presented to the Court, are traditionally left for the jury. The *Daubert* analysis focuses on the methodology underlying an expert's opinion, not the expert's conclusions.[35] Therefore, the focus of admissibility under *Daubert* is the reliability of the experts' methods, not their correctness.[36] The trial court is not empowered "to determine which of several competing scientific theories has the best province."[37] As long as the expert's testimony falls within "the range where experts may reasonably differ," then it is up to the jury to decide among the competing views.[38]

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v. Ford Motor Co., 520 F.3d 237, 243 (3d Cir. 2008).

[33] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596, 113 S. Ct. 2786 (1993).

[34] *In re TMI Litig.*, 193 F.3d 613, 692 (3d Cir. 1999) (amended on other grounds).

[35] *Daubert*, 509 U.S at 595.

[36] *Id*. at 585. *See also Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 1969 (1988); Fed. R. Evid. 702.

[37] *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 15 (1st Cir. 2011) (internal quotation marks and citations omitted).

[38] *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153, 119 S. Ct. 1167 (1999); *In re: Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, 2016 WL 4039286, at *2 (E.D. Pa. July 28, 2016) ("Fed. R. Evid. 702 and *Daubert* put their faith in an adversary system designed to expose flawed expertise."); *United States v. Mitchell*, 365 F.3d 215, 244–45 (3d Cir. 2004) (citations omitted) ("As long as an expert's scientific testimony rests upon 'good grounds, based

Third, causal inference is a matter of judgment about the totality of the scientific evidence. "Drawing causal inference . . . requires judgment and searching analysis based on biology, of why a factor or factors may be absent despite a causal relationship, and vice versa."[39] As noted in the *Reference Manual on Scientific Evidence*: "Although the drawing of causal inference is informed by scientific expertise, it is not a determination that is made by using an algorithmic methodology."[40] As this judgment is a scientific determination, it can evolve "as new evidence develops" because "the scientific enterprise must always remain open to reassessing the validity of past judgments."[41] The judgment of whether to draw a causal inference can lead to disagreement amongst experts in the field.[42] In the end, deciding whether associations are causal typically is not a matter of statistics alone, but also rests on scientific judgment."[43] Defendants' brief is silent on this essential point.

Fourth, a causal inference requires an examination of the totality of the

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on what is known,' it should be tested by the adversary process— competing expert testimony and active cross–examination . . . .").

[39] *Reference Manual on Scientific Evidence*, Federal Judicial Center, Third Edition (2011) ("Ref. Man.") at 600.

[40] *Id.*

[41] *Id.* at 598.

[42] *See, e.g., In re Neurontin Marketing, Sales Practices, and Products Liability Litigation,* 612 F. Supp. 2d 116, 149 (D.Mass. 2009) (causation supported by biologic plausibility notwithstanding the "robust debate in the scientific community" regarding the proposed mechanism); *Milward*, 639 F.3d at 18; *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 174 F. Supp. 3d 911 (D.S.C. 2016); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1833173, at *9 (N.D. Ill. May 8, 2017).

[43] *Ref. Man.* at 20, 21, 222, 553, 565, 591, 599 and 600.

scientific evidence. "Scientific inference typically requires consideration of numerous findings, which, when considered alone, may not individually prove the contention."[44] This is how science outside of the courtroom functions. There is simply no definitive check-list or magic formula for making scientific judgments. As explained in the *Reference Manual*:

> It appears that many of the most well-respected and prestigious scientific bodies (such as the International Agency for Research on Cancer (IARC), the Institute of Medicine, the National Research Council, and the National Institute for Environmental Health Sciences) consider all the relevant available scientific evidence, taken as a whole, to determine which conclusion or hypothesis regarding a causal claim is best supported by the body of evidence. In applying the scientific method, scientists do not review each scientific study individually for whether by itself it reliably supports the causal claim being advocated or opposed.[45]

The Third Circuit, as well as numerous other courts, have endorsed an expert's use of the "weight of the evidence" approach to assessing the "totality" of evidence for evaluating causation.[46]

Fifth, science does not demand certainty. Nor does the law. Under Third

[44] *Id.* at 19–20; *see also Milward*, 639 F.3d at 26 (reversing the district court's exclusion of expert testimony based on an assessment of the contribution of individual studies and finding that the "weight of the evidence" properly supported the expert's opinion).
[45] *Ref. Man.* at 600.
[46] *See In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 796– 797 (3d Cir. 2017) (citing *Milward*, 639 F.3d at 17 ("[t]he court treated the separate evidentiary components of [the expert's] analysis atomistically, as though his ultimate opinion was independently supported by each."); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 607 (D.N.J. 2002); *In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, 198 F. Supp. 3d 446, 458 (E.D. Pa. 2016); *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003) (rejecting defense *Daubert* challenges which "isolate these sources [of evidence] rather than considering the whole").

Circuit *Daubert* standards, the trial court should not impose "a standard of scientific certainty . . . beyond that which *Daubert* envisions."[47] Plaintiffs also are not required to present evidence that is conclusive or unequivocal. "[I]n epidemiology hardly any study is ever conclusive, and we do not suggest that an expert must back his or her opinion with published studies that unequivocally support his or her conclusions."[48] Science and medicine often do not lead to certainty and the law does not require certainty.[49]

B. Defendants' Motion Improperly Requests That the Court Weigh The Evidence On The Relationship Between Talcum Powder Products And Ovarian Cancer

In the context of a *Daubert* motion, the question before the Court is not whether the movant's experts or the respondent's experts are correct or even what conclusion the Court would come to if it were the trier of fact. The sole question is whether each challenged expert used a reliable methodology.[50] Defendants' motion nevertheless attempts to convince the Court that it is "right" while disguising its arguments as a methodological challenge.

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[47] *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 86 (1st Cir. 1998).
[48] *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 354 (5th Cir. 2007).
[49] *Milward*, 639 F.3d at 22 (quoting *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)).
[50] *See, In re Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings*, 2017 WL 1833173, at *9 ("At this stage, it is not the Court's role to choose between competing studies…the studies "merits and demerits…can be explored at trial.") (citation omitted); *In re Roundup Prod. Liab. Litig.*, 2018 WL 3368534, at *2–3 (N.D. Cal. July 10, 2018) ("So long as an opinion is premised on reliable scientific principles, it should not be excluded by the trial judge; instead the weaknesses in an unpersuasive expert opinion can be exposed at trial, through cross examination or testimony by opposing experts").

In seeking to exclude Dr. Clarke-Pearson's case-specific opinions, J&J has sought to pit its experts' "conclusions" against Clarke-Pearson's "conclusions," to inappropriately exclude the "flawed" opinions J&J does not agree with. The fact that experts reach different conclusions about a matter, however, is not a methodologic issue and is no basis for a *Daubert* challenge. Moreover, as set forth below, many of Defendants' conclusions are based on inaccurate and unsupported facts.

The *Reference Manual* notes that the question of causal inference is not subject to a mathematical or mechanical formula and a difference in opinion is simply not the basis to exclude a qualified experts' opinion.[51] A causal inference requires an examination of the *totality of the scientific evidence*. When an issue involves a multitude of evidence, appropriate scientific methodology requires consideration of the cumulative effect of all of the scientific evidence and not only certain parts. "Scientific inference typically requires consideration of numerous findings, which, when considered alone, may not individually prove the contention."[52]

As Leon Gordis, MD, an editor of the *Reference Manual* observed in his textbook *Epidemiology* (5th Ed):

> Although it may be a desirable goal to place causal inferences on a firm quantitative and structural foundation, at present we do not have all of the information needed for doing so. [The Bradford Hill aspects] should

[51] *Ref. Man.* at 600 (rejecting an "algorithmic methodology" to determine causation).
[52] *Ref. Man.* at 19–20.

> therefore be considered to be only guidelines that can be of most value when coupled with reasoned judgment about the entire body of available evidence, in making decisions about causation.[53]

Reasoned judgment and difference of opinion are part of the process. In his Cancer Epidemiology textbook entitled *Risk Factors for Cancer In the Workplace*, the PSC's expert, Jack Siemiatycki, Ph.D, bluntly observed the simple truth: "Equally competent scientists, examining the same information, can arrive at different [causal] conclusions."[54]

Defendants' motion does not describe either a true *methodologic* challenge or a legitimate contention that Dr. Clarke-Pearson *refused* to consider relevant evidence (*e.g.*, *In Re Zoloft)*. That Dr. Clarke-Pearson's case-specific opinions may be different than those of Defendants' experts simply presents a jury question. The real question is whether there is *any* evidence that Dr. Clarke-Pearson engaged in unreliable methodologies in reaching his opinions. As set forth below, there is none.

C. In Dr. Clarke-Pearson's Case-Specific Analyses, He Methodically Considered All Relevant Factors, Ruling In And Ruling Out Factors With Regards To Each Plaintiff.

Differential diagnosis is a method used by medical experts to determine the cause of a plaintiff's injury by systematically ruling out alternative causes.[55] The Third Circuit has held that differential diagnosis is a reliable method for determining

[53] Leon Gordis, *Epidemiology* Chapter 14 at 260. (5th ed. 2013), attached as **Exhibit 26**.
[54] Jack Siemiatycki *Risk Factors for Cancer In the Workplace*, at 298, attached as **Exhibit 27**.
[55] *Heller v. Shaw Industries, Inc.***,** 167 F.3d 146, 156 (3d Cir. 1999) (allowing the expert's opinions based on a differential diagnosis).

causation in product liability cases.[56]

"The first step in properly conducting a differential diagnosis is for the expert to 'rule[ ] in' all plausible causes for the patient's condition by compiling a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration."[57] An examination of the plaintiff's medical records is a reliable method.[58] "At this stage, the issue is which of the competing causes are *generally* capable of causing the patient's symptoms or mortality."[59]

"Second, after the expert 'rules in' plausible causes, the expert then must 'rule out' those causes that did not produce the patient's condition by engaging in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case."[60] "A medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness."[61] "[T]hat is a more stringent standard for a medical expert's differential diagnosis than is required under Rule 702."[62]

> [T]o require the experts to rule out categorically all other possible

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[56] *Id.*
[57] *Creanga v. Jardal*, 886 A.2d 633, 639 (N.J. 2005) (internal citations omitted) (finding the expert's differential diagnosis was properly conducted and therefore admissible).
[58] *Kannankeril v. Terminix Intern., Inc.,* 128 F.3d 802, 807 (3d Cir. 1997) (allowing expert's testimony based on differential diagnosis).
[59] *Creanga*, 886 A.2d at 639 *(internal citations omitted) (emphasis in original).*
[60] *Id.* (internal citations omitted).
[61] *Heller***,** 167 F.3d at 156.
[62] *Id.*

> causes for an injury would mean that few experts would ever be able to testify....
>
> ... Obvious alternative causes need to be ruled out. All possible causes, however, cannot be and need not be eliminated before an expert's testimony will be admitted.[63]

Only "where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable."[64] The rule requires only that the expert should "employ[] sufficient diagnostic techniques to have good grounds for his or her conclusion."[65] The "hallmark" of differential diagnosis is for the expert to identify several possible causes, consider the alternatives, and rule them out to reach his conclusion with a reasonable degree of medical certainty.[66]

The methodology described above is precisely the methodology Dr. Clarke-Pearson used in his case-specific analyses. For each plaintiff, he first describes the materials he reviewed: all the available medical records, deposition testimony, Plaintiff Profile Form and Dr. Godleski's expert report or pathological findings.[67] He then spends several pages for each plaintiff describing in detail her medical history, cancer diagnosis, cancer treatment, and related injuries. Dr. Clarke-Pearson

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[63] *Id.*, citing Daniel J. Capra, *The* Daubert *Puzzle,* 32 Ga.L.Rev. 699, 728 (1998).
[64] *Heller*, 167 F.3d at 156.
[65] *Id.*
[66] *Poust v. Huntleigh Healthcare*, 998 F.Supp. 478, 497 (D.N.J. 1998) (admitting expert's testimony over objections that he failed to consider every possible cause).
[67] 2d Amd. Converse Rpt. at 17; 2d Amd. Newsome Rpt. at 18; 2d Amd. Rausa Rpt. at 18.

then describes his differential diagnosis for each plaintiff, the first step of which is ruling in all plausible causes for the plaintiff's condition by compiling a comprehensive list of known risk factors and protective factors associated with ovarian cancer. He then addresses each factor, ruling out the factors that did not cause the plaintiff's ovarian cancer by engaging in a process of elimination, eliminating risk factors and protective factors that did not apply. Through a continuing examination of the evidence, Dr. Clarke-Pearson reaches his conclusion as to the most likely cause of the findings in that particular case, to a reasonable degree of medical and scientific certainty. His differential diagnoses are set forth in detail in his case-specific expert reports. [68]

For each plaintiff, he addressed the following questions:

1. Is the genital use of talcum powder associated with Plaintiff's type of ovarian cancer?
2. Did the plaintiff have a history of sufficient perineal use of talcum-containing products?
3. Was there talc and/or asbestos found in her pathologic tissue, providing additional evidence of usage?
4. Was there enough time between the onset of use and the diagnosis of ovarian cancer to account for the expected latency period associated with the development of ovarian cancer?
5. Were other risk factors or protective factors present and, if so, what was their contribution to the development of ovarian cancer?

He also considered whether the plaintiff had the following risk factors for ovarian cancer: inherited genetic mutations; family history of ovarian or breast cancer;

[68] 2d Amd. Converse Rpt. at 17-19; 2d Amd. Newsome Rpt. at 18-19; 2d Amd. Rausa Rpt. at 18-20.

increasing age; nulliparity; early menarche; late menopause; high fat diet; infertility; endometriosis; polycystic ovarian syndrome; hormone replacement therapy; IUD use; pelvic inflammatory disease; and obesity. Lastly, for each, he assessed whether the plaintiff had the following protective factors: multiparity; breastfeeding; oral contraceptive use; tubal ligation; and hysterectomy.

In spite of these comprehensive analyses, Defendants suggest that Dr. Clarke-Pearson did not adequately consider each plaintiff's medical history. To the contrary, in addition to his case-specific reports as quoted above, Dr. Clarke-Pearson specifically addressed each potential risk factor in his depositions. Oddly enough, Defendants cite much of Dr. Clarke-Pearson's deposition testimony in support of their argument that he did not consider these factors.

Ms. Converse - [redacted] Dr. Clarke-Pearson testified as follows:

- [redacted]

[69] Motion at 7.
[70] Deposition of Daniel L. Clarke-Pearson, M.D., Aug. 26, 2021, at 272:16-273:5, attached as **Exhibit 28**.

- [redacted]

[redacted]

[redacted]

Ms. Newsome – [redacted]. Dr. Clarke-Pearson testified as follows:

- [redacted]

[redacted]

[redacted]

[71] Dep. of Clarke-Pearson, Aug. 26, 2021, at 266:11-14.
[72] Deposition of Daniel L. Clarke-Pearson, M.D., March 8, 2024, at 282:6-10, attached as **Exhibit 29**.
[73] Dep. of Clarke-Pearson, Aug. 26, 2021, at 267:6-7.
[74] Dep. of Clarke-Pearson, Aug. 27, 2021 at 615:2-616:6, attached as **Exhibit 30**.
[75] *Id.* at 591:14-19.
[76] 2d Amd. Newsome Rpt. at 19. Notably, Defendants did not begin to allege that Ms. Newsome had a history of endometriosis until after Dr. Clarke-Pearson's fourth and last deposition, so his deposition does not address that contention in detail.

- [redacted]
- [redacted]

Ms. Rausa – [redacted]

[redacted] Dr. Clarke-Pearson testified as follows:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[77] *Id.* at 583:3-5.
[78] *Id.* at 600:20-21.
[79] Motion at 8.
[80] Dep. of Clarke-Pearson, Aug. 27, 2021, at 672:7-11.
[81] *Id.* at 622:15.
[82] *Id.* at 662:17-18 (emphasis added).
[83] *Id.* at 624:20-625:10.
[84] *Id.* at 664:3-4.
[85] *Id.* at 666:19-22.

Given the detailed analysis employed by Dr. Clarke-Pearson with regard to each plaintiff, there is no basis for Defendants' claims (1) that he did not "rule in" talc, when he addressed talc directly in questions 1-3 of each differential diagnosis; or (2) that he did not "rule out" other potential causes of the plaintiffs' cancers, when he specifically lists each known risk factor and whether or not each applies to each plaintiff. Dr. Clarke-Pearson "identif[ied] several possible causes, consider[ed] the alternatives, and rule[d] them out to reach his conclusion with a reasonable degree of medical certainty.[86] Based on New Jersey and Third Circuit case law, her methodologic approach meets the requirements of admissibility under Rule 702.

D. Even If Defendants Had Not Misstated Dr. Clarke-Pearson's Testimony And Quoted It Out Of Context, Their Arguments Go To The Weight Of The Evidence, Not Its Admissibility.

Defendants' Motion spends considerable time attacking Dr. Clarke-Pearson for his opinions with regards to the relative and attributable risk of talcum powder use. As was done at the time of his deposition, Defendants have misstated his testimony and taken it out of context. To clarify his testimony regarding the increased risk of ovarian cancer with talcum powder use, Dr. Clarke-Pearson testified that "30 percent is a good place to start."[87] He explained that "we would then have [to] go and look at other data, look at long-term use, and frequency of

[86] *Poust*, 998 F.Supp. at 497.
[87] Dep. of Clarke-Pearson, March 8, 2024, at 327:11-12.

use," because "the epidemiological literature does say there's a higher risk in women that use talc over a long period of time."[88] In other words, "there's a range" of risk; 30 percent is "a ballpark number."[89] The three plaintiffs at issue "have used talcum powder extensively. And the epidemiologic data says the extensive use does increase the risk to more than 30 percent."[90] Therefore, Dr. Clarke-Pearson referred to the Penninkilampi (2018) article, which addresses the risk of epithelial ovarian cancer in subjects with extensive long-term use.[91] It was based on this article that Dr. Clarke-Pearson made clear that for heavy users of talcum powder, like these three plaintiffs, the risk was more likely 1.42 (or 42%).[92]

Defendants argue that Dr. Clarke-Pearson's opinion "reflects either a fundamental misunderstanding of math or a deliberate misinterpretation because an increased risk of 42 percent is not the same thing as contributing 42 percent to a patient's disease."[93] Inexplicably, in reference to this statement Defendants cite to Dr. Clarke-Pearson's testimony in which he agrees that "increasing your risk by 42 percent does not mean a 42% risk."[94] Thus, it seems more accurate to say that it is

[88] *Id.* at 327:16-21.
[89] *Id*. at 327:25-328:3.
[90] *Id.*at 329:6-9.
[91] *Id.* at 332:1-10, *citing* Penninkilampi & Eslick, Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis, 29(1) Epidemiology 41, 44 (2018), attached as **Exhibit 31**.
[92] *Id.*
[93] Motion at 6.
[94] Dep. of Clarke-Pearson, March 8, 2024, at 335:20-24.

Defendants' brief that "reflects a fundamental misunderstanding or a deliberate misinterpretation" of Dr. Clarke-Person's testimony.

Even if Defendants had not misstated Dr. Clarke-Pearson's testimony and quoted it out of context, their arguments go to the weight of his opinions, not their admissibility. As stated by the Third Circuit, "we emphasized that the district court should take care not to mistake credibility questions for admissibility questions. If the medical expert's opinion on causation has a factual basis and supporting scientific theory that is reliable, it should be admitted."[95] As detailed above, Dr. Clarke-Pearson's opinion has a factual basis and reliable, supporting scientific theory; thus, it should be admitted. Defendants may address any questions they have regarding credibility on cross-examination.

E. Dr. John Godleski's Opinions Are Not Dispositive to the Admission Of Dr. Clarke-Pearson's Opinions.

Dr. Godleski conducted a pathologic evaluation of the tissue removed from Ms. Converse, Ms. Newsome and Ms. Rausa and discovered damning evidence: all three women had talc particles, talc fibers, and/or asbestos in their pathologic tissue. Because Dr. Clarke-Pearson typically reviews and considers pathology in his medical practice, he reviewed these findings and included them on the materials he considered. While Dr. Clarke-Pearson did not consider these findings a requirement

[95] *Heller,* 167 F.3d at 157 (internal citations omitted).

for his causation opinions, they were informative, as "the presence of talc particles or mineral fibers in pathology lends support to causation."[96] Even if Dr. Clarke-Pearson had not been provided with any of Dr. Godleski's reports, he would still be able to conclude that talcum powder use contributed to the risk of ovarian cancer in these three women.[97]

Therefore, while helpful, Dr. Clarke-Pearson's opinions do not rely on Dr. Godleski's report, and thus Dr. Godleski's opinions are not dispositive to the issue of whether Dr. Clarke-Pearson's testimony should be excluded. To the extent Defendants argue that Dr. Godleski's opinions are unreliable or inadmissible, those arguments will be addressed in Plaintiffs' Steering Committee's Opposition to Defendants' Motion to Exclude the Opinions of Dr. John Godleski.

V. CONCLUSION

For these reasons, Defendants' motion to exclude Dr. Clarke-Pearson's case-specific opinions should be denied.

Respectfully submitted,

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[96] 2d Amd. Converse Rpt. at 17; 2d Amd. Newsome Rpt. at 18; 2d Amd. Rausa Rpt. at 18.
[97] Dep. of Clarke-Pearson, Aug. 26, 2021, at 635:9-13.

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